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HEALTH

Survey of FDA Approvals Questions Extensions for Patents, Fuels Feud

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DRUG DEVELOPMENT

- Why Drug Makers Are Failing in Quest for New Blockbusters[4] 04/18/02
- As Claritin Goes Generic, Schering-Plough Pushes Close Sibling[5] 03/22/02
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WASHINGTON -- A new study that finds a lack of innovation in the prescription-drug industry has ignited a fresh fight between the pharmaceuticals industry and a nonprofit group with ties to insurance companies.

The study, released Tuesday night by the Washington-based National Institute for Health Care Management Foundation (www.nihcm.org[1]), finds that two-thirds of the prescription drugs approved by the Food and Drug Administration between 1989 and 2000 were identical to existing drugs or modified versions of them. Only about one-third of the drugs approved by the FDA during the time period were based on new "molecular entities" that treat diseases in novel ways, the group said.

The foundation, which has tangled with the drug industry before, said the trend toward incremental changes in drugs is accelerating in part because pharmaceuticals firms are seeking to extend lucrative patents on big-selling drugs.

SOARING DRUG PRICES

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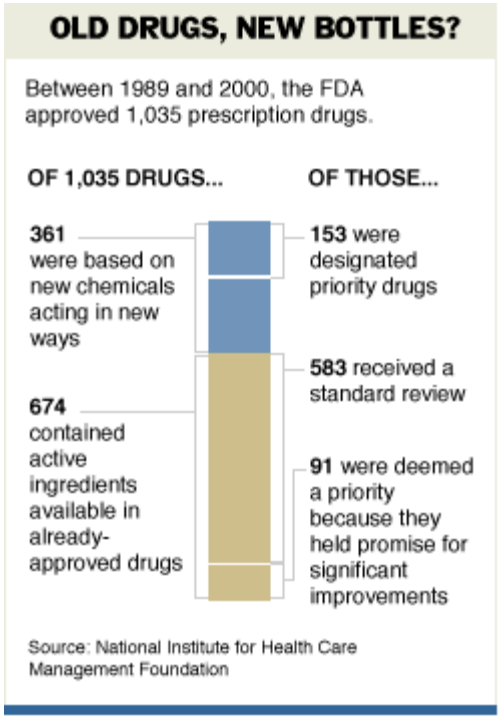
Drug prices are soaring, as the pharmaceutical industry invests more in research and development and gets less out of it. Read the Journal's series of Page One stories[3] on the embattled industry.

Members of Congress are debating the high costs of drugs and whether patent laws should be tightened to make it harder for pharmaceuticals companies to win patent extensions for brand-name medicines. The report -- which said such patent changes could restrain drug spending while increasing access to needed medications -- might bolster these efforts. Generic-drug makers, meanwhile, have launched several high-profile legal challenges to patent extensions filed by large pharmaceuticals companies, saying they are merely stall tactics meant to stave off competition from cheaper forms of drugs whose patents are expiring. A judge in New York is currently hearing one of the biggest such cases, involving **AstraZeneca** PLC's

patent claims on its big-selling ulcer drug, Prilosec.

The Pharmaceutical Research and Manufacturers of America, a trade group representing the drug industry, blasted the report as "little more than a political and financially motivated cheap shot." Richard Smith, vice president for policy and research, called the group a "tool" of the **Blue Cross** and Blue Shield companies, which, he said, want to hold down drug costs.

He also expressed frustration about the report's implicit criticism of "me-too drugs." He said a choice of drugs is needed to ensure proper treatment is available. For example, he said, as many as one-half of patients who are treated for depression don't respond to the first antidepressant taken, but do improve when they switch to another one.



It is well known that drug development is often incremental. But recently, drug-company labs have run into a frightening dry patch, forcing drug companies to try to extend the franchises on their most popular drugs. For instance, **Schering-Plough** Corp.'s new Clarinex is almost identical to its huge-selling allergy pill Claritin. Nonetheless, Schering-Plough is hoping to persuade Claritin users to switch to the new pill since Claritin's patent is due to expire in December and generic entrants will steal sales.

The study also said only 153 "highly innovative drugs" -- which it defined as those that contain new active ingredients and also provide significant clinical improvement -- were approved between 1989 and 2000. That was 15% of the 1,035 drugs approved in the period, and included **Pfizer** Inc.'s cholesterol drug, Lipitor, and **Merck** & Co.'s osteoporosis drug, Fosamax.

Nancy Chockley, president of the NICHM, defended the report, saying many consumers don't realize that "highly innovative drugs are rare." She said some incrementally improved drugs do provide additional choices, but that is different from breaking ground with a new molecular entity.

Ms. Chockley also said she doesn't try to hide the fact that 40% of the foundation's funding comes from managed-care plans, and that most of the people sitting on the board of the nonprofit organization come from companies that provide Blue Cross and Blue Shield health plans. But, she said, the foundation's biggest chunk of funding comes from the federal government, and "we try very hard to bend over backwards for our work to be completely clean."

She said the study wasn't shown to the board of directors ahead of time. Instead, it was reviewed by the group's advisory board, which includes John Cogan, a former Reagan administration budget official who is a senior fellow at Stanford University's Hoover Institution; Robert Reischauer, a former head of the Congressional Budget Office who is president of the Urban Institute; and Uwe Reinhardt, a Princeton University professor.

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